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DEC 3 1 2003

510(k) Summary
AMS Large Pore Polypropylene Mesh

510(k) Number _____

Date of Summary Preparation:
November 17, 2003

Submitter/Contact Person:
Elsa A. Linke
Regulatory Affairs Specialist
American Medical Systems
10700 Bren Rd. W
Minnetonka, MN 55343

Phone: (952) 930-6000
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Device Name and Classification:
Trade Name: AMS Large Pore Polypropylene Mesh
Common/Usual Name: Surgical Mesh
Classification Name: Surgical Mesh, polymeric
Product Code: FTL
Classification: Class II

Manufacturing Location:
American Medical Systems, Inc.
10700 Bren Rd. West
Minnetonka, MN 55343

Predicate Devices:
Gynemesh Prolene Soft Mesh – K013718
Ethicon Prolene Soft Mesh - K001122
AMS Sacral Colpopexy Sling – K010931

Indications for Use:
The AMS Large Pore Polypropylene Mesh is indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended, either as mechanical support or bridging material for the fascial defect.

Device Description:
The AMS Large Pore Polypropylene Mesh is a knitted mesh of polypropylene fibers. The mesh can be cut to any desired shape or size and resists unraveling.

Summary of Testing

The material used in the AMS Large Pore Polypropylene Mesh has been demonstrated to be biocompatible.

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In addition, the AMS Large Pore Polypropylene Mesh has been tested for a variety of mechanical characteristics in accordance with FDA's Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh and has been shown to be equivalent to the listed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 31 2003

Ms. Elsa A. Linke
Regulatory Affairs Specialist
American Medical Systems
10700 Bren Road, West
Minnetonka, Minnesota 55343

Re: K033636
Trade/Device Name: AMS Large Pore Polypropylene Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Polymeric surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: November 17, 2003
Received: November 19, 2003

Dear Ms. Linke:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K033636

INDICATIONS FOR USE ENCLOSURE

510(k) Number: _____

Device Name: AMS Large Pore Polypropylene Mesh

Indications for Use: The AMS Large Pore Polypropylene Mesh is indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended, either as mechanical support or bridging material for the fascial defect.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

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